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June 10, 2019

Mr. Stiven Foster
Office of Land and Emergency Management
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

Re: "Draft *Interim Recommendations for Addressing Groundwater Contaminated with PFOA and PFOS".* Docket ID No. EPA-HQ-OLEM-2019-0229

Dear Mr. Foster:

The American Petroleum Institute (API) is the primary trade association of America's oil and natural gas industry representing more than 625 member companies involved in all aspects of the oil and natural gas industry, including exploration, production, refining, transportation, distribution, and marketing of petroleum and petroleum products.

The members of API are dedicated to continuous efforts to improve the compatibility of our operations with the environment while economically developing energy resources and supplying high quality products and services to consumers. We recognize our responsibility to work with the public, the government, and others to develop and to use natural resources in an environmentally sound manner while protecting the health and safety of our employees and the public.

On April 25, 2019, the U.S. Environmental Protection Agency (EPA) released for comment, their draft "Interim Recommendations for Addressing Groundwater Contaminated with PFOA and PFOS". EPA is currently proposing the use of the 2016 Drinking Water Health Advisory levels for PFOA[1] and PFOS[2] as interim recommendations for addressing groundwater contamination. The 2016 Health Advisory was

[1] USEPA, 2016a. Drinking Water Health Advisory for Perfluorooctanoic Acid (PFOA). EPA 822-R-16-005. https://www.epa.gov/sites/production/files/2016-05/documents/pfoa_health_advisory_final_508.pdf

[2] USEPA, 2016b. Drinking Water Health Advisory for Perfluorooctanoic Sulfonate (PFOS). EPA 822-R-16-004. https://www.epa.gov/sites/production/files/2016-05/documents/pfos_health_advisory_final_508.pdf

based upon the Agency's assessment of the best-available science at the time. EPA has stated that both the Health Advisory and the Interim Groundwater Recommendations may change as new information becomes available. EPA should further commit to revising the guidance to increase or decrease the threshold as warranted by scientific evidence as our understanding of the hazards and interactions of these compounds with environment is constantly evolving.

1. **API believes the EPA should clarify language in the recommendations proposed by this guidance to ensure proper application.**

   The interim recommendations require the use of 70 ppt as the Preliminary Remediation Goals (PRGs) for groundwater that is a current or potential source of drinking water. The term potential sources of drinking water makes the boundaries for the use of the PRGs unclear. As the recommendation is written, it would imply that any groundwater that has been or may be designated as drinking water, regardless of current use, would have to utilize these goals for cleanup. The agency should clarify the definition of potential source of drinking water in this case to provide boundaries for application of the interim guidance.

2. **API does not agree with the Agency's application of a drinking water advisory level as a groundwater threshold.**

   The guidance further indicates that in situations where groundwater is being used for drinking water, EPA expects that responsible parties will address levels of PFOA and/or PFOS over 70 ppt. While this is consistent with current interim guidance, it fails to clarify that the levels should be addressed at the point of use, just prior to delivery to the customer. Since risk-based concentrations are still being developed and can significantly change, it is premature to require goals to be set for cleanup that extends beyond groundwater sources immediate to the point of use. At this stage, protection of human health can be efficiently and effectively addressed by managing contaminant concentrations at the point of use rather than the entire potential source.

3. **EPA should also take into consideration scientific information more recent than 2016 for informing PRGs and HQs. This newer information indicates that the approaches used by EPA to calculate the 2019 PRGs and recommended HQs for PFOAS and PFOA are insufficiently predictive of humans and are overly conservative.**

EPA's proposed Preliminary Remediation Goals (PRGs) and HQs for PFOS and PFOA are based on science from 2016. More recent data from a Phase I clinical trial and information from Health Canada's recent Guidelines for Drinking Water Quality for PFOS and PFOA were not considered. Both provide perspective on the relative magnitude of EPA's PRGs and HQs and indicate aspects of the risk assessment process that may be problematic.

A clinical study by Convertino *et al.* [3] became available in 2018. In this study, cancer patients were orally administered very high doses of ammonium perflurooctanoate, which is converted to PFOA in the blood. No major health effects were observed at doses up to 16 mg/kg/week[4]. To provide perspective, this weekly dose is 800,000-fold greater than the acceptable daily dose estimated by EPA using 2016 science[5]. As more an "apples-to-apples" comparison of effects in the same organ, the only liver effect observed in people was *decreased* cholesterol. This weekly dose is 100,000-fold greater than the acceptable estimated daily dose protective of the liver according to EPA in the 2016 health advisory[6]. This clinical study strongly suggests indicates that the 2016 science and approaches used by EPA to calculate the respective 2019 PRG and HQ for PFOA are not predictive of humans and result in unreasonably conservative values.

A clinical study is not available for PFOS. The 2016 HA for PFOS used different laboratory animal-derived endpoints as the basis for the human health risk assessment, but nonetheless utilized the same PBPK model and similar rodent-to-human extrapolation and uncertainty factor approaches as those to establish the PFOA HA. Therefore, the 2016 HA and 2019 PRG for PFOS are also likely not predictive of responses in humans.

[3] Convertino, M., Church, T.R., Olsen, G.W., *et al.* Stochastic Pharmacokinetic-Pharmacodynamic Modeling for Assessing the Systemic Health Risk of Perfluorooctanoate (PFOA). *Toxicological Sciences.* 163(1): 293-306. 2018.

[4] Doses were 50 mg to 1200 mg and the average participant weight was 75 kg. The doses were therefore 50 mg/75 kg = 0.67 mg/kg to 1200 mg/75 kg = 16 mg/kg.

[5] RfD for PFOA in 2016 HA is 0.00002 mg/kg/day. (16 mg/kg/week) ÷(0.00002 mg/kg/day) = 800,000.
[6] RfD for liver effects in 2016 HA is 0.00015 mg/kg/day. . (16 mg/kg/week) ÷(0.00015 mg/kg/day) = 106,600.

2018 was also the year that Health Canada published Guidelines for Drinking Water Quality for both PFOS (Maximum acceptable concentration (MAC) = 600 ng/L)[7] and PFOA (MAC=200 ng/L)[8]. These values are approximately 3- to 8-fold greater than EPA's PRGs. Health Canada's assessments differ from EPA's, most notably in the application of PBPK models. (The approaches used to quantify interspecies differences are likely to have a large impact on the magnitude of recommended values).

The current PRGs for PFOS and PFOA are based on data from animal studies. This approach required EPA to make several assumptions and adjustments related to interspecies differences that are not necessary with controlled human (clinical) studies. These assumptions and adjustments may introduce errors that result in unreasonably conservative values. These potential sources of error include (but may not be limited to): use of endpoints in animals for risk assessment that are not relevant to humans, use of a PBPK model that does not accurately predict human-equivalent doses, application of uncertainty factors that are too large in magnitude, and/or residual overlap in uncertainty between the PBPK model and the interspecies uncertainty factor (which was split into 1X pharmacokinetic and 3X pharmacodynamic components). The results of Convertino and Health Canada indicate that EPA's approach is leading to overly conservative PRGs with the potential sources of error listed above.

Additionally, both the Convertino study and the Health Canada results indicate that a far greater hazard quotient (HQ) than 0.1 for PFOS and PFOA would still be sufficiently protective for co-exposures to other substances of concern.

[7] Guidelines for Canadian Drinking Water Quality, Guideline Technical Document, Perflurooctane Sulfonate (PFOS). Health Canada. Ottawa, Ontario. December 2018. https://www.canada.ca/content/dam/canada/health-canada/migration/healthy-canadians/publications/healthy-living-vie-saine/guidelines-canadian-drinking-water-quality-guideline-technical-document-perfluorooctane-sulfonate/PFOS%202018-1130%20ENG.pdf.

[8] Guidelines for Canadian Drinking Water Quality, Guideline Technical Document, Perflurooctanoic Acid (PFOA). Health Canada. Ottawa, Ontario. December 2018. https://www.canada.ca/content/dam/hc-sc/documents/services/publications/healthy-living/guidelines-canadian-drinking-water-quality-technical-document-perfluorooctanoic-acid/document/PFOA_2018-1130-eng.pdf

Please contact Timothy Steffek (steffekt@api.org) or Jessica Ryman-Rasmussen (rymanj@api.org) with any questions or should you require additional information from API.

Sincerely,

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